Remarks

Claims 18 and 31-34 are now in the case. Claim 18 has been amended. Claims 17, 19, 21 and 30 have been cancelled. Claims 31-34 have been added. Support for the amendments can be found in the claims as originally filed and throughout the specification, see in particular page 8; no new matter has been added.

Please note that the Docket Number has been changed, it is now 2861-US-CNT2.

Claim Objections

Claims 17 and 19 are objected to as being of improper dependent form.

Claims 17 and 19 have been cancelled. Applicants respectfully request that the claim objections be withdrawn.

Rejection under 35 U.S.C. § 101 and § 112, first paragraph:

Claims 17-19, 21 and 30 are rejected under § 101 and § 112, first paragraph, as allegedly lacking patentable utility. The Office states "the issue is not that of the presence or absence of a credible utility but whether or not a claimed invention possesses a specific and substantial *in vitro* or *in vivo* utility". The Office maintains its rejection based on the allegation that the specification does not indicate that Applicant knew of a specific utility for the SVPH1-26 disintegrin domain.

Applicant respectfully traverses these grounds for rejection. Applicant does not accede to the Office's assertions, however, merely to advance the claims toward allowance, claims 17, 19, 21 and 30 have been cancelled and new claims 31-34 have been added. Applicant reserves the right to pursue the cancelled matter in continuation applications.

Utility under 35 U.S.C. §101 is a minimal threshold issue that can be satisfied by a showing of any use that is "substantial," "credible," and "specific." (MPEP §2107). A small degree of utility is sufficient. Thus, as a matter of Patent Office practice, a specification that provides disclosure of a utility that corresponds in scope to the subject matter sought to be patented and that is substantial, credible, and specific *must* be taken as sufficient to satisfy the utility requirement of 35 U.S.C. §101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility.

The Office alleges that the specification does not indicate a specific utility for the SVPH1-26 disintegrin domain. The claims under examination now recite adamalysin

polypeptides corresponding to SVPH1-26 polypeptides comprising, among other things, a protease domain. Applicant teaches that SVPH1-26 polypeptides, like other ADAM proteins, comprises a protease or catalytic domain and like other ADAM proteins, the proteinase activity is likely involved in the shedding of membrane proteins, see the specification at page 9, first full paragraph. Use of protease proteins to shed membrane proteins and the inhibition of protease proteins is specific, substantial and credible.

The claimed SVPH1-26 polypeptides share the conserved domain structures found in mammalian adamalysins (ADAMS), see the specification at page 8, second paragraph. SVPH1-26, like other ADAM proteins such as ADAMs 1-6, is testis-specific or predominantly expressed in the testis, see page 58, Example 1. The testis-expressed ADAMs 1-6 have all been implicated in fertilization and/or spermatogenesis, see the specification, paragraph bridging pages 8-9. Applicant provides that SVPH1-26 is testis-expressed ADAM protein involved in fertilization and/or spermatogenesis, see the specification at page 9, first paragraph. Applicant notes that ADAM1 (fertilin α), found to be required for the fusion of sperm and egg, has no human equivalent and teaches that SVPH1-26 may be the human equivalent of this protein, see the specification at page 9, first paragraph.

Like other testis-expressed ADAM proteins SVPH1-26 polypeptides are associated with spermatogenesis and/or fertilization. For example, inhibitors of SVPH1-26 polypeptides, including anti-SVPH1-26 antibodies, antisense polynucleotides, and molecules comprising SVPH1-26 polypeptide disintegrin domain can be used to inhibit the function of endogenous, testis-expressed SVPH1-26 polypeptides. This use is specific, because not all polypeptides, antibodies, or polynucleotides will bind to testis cells, and certainly not with the specificity associated with the claimed SVPH1-26 polypeptides. Neither can all polypeptides, antibodies, or polynucleotides be used to inhibit testis-expressed proteins and by association modulate spermatogenesis and/or fertilization. This use is also substantial in that there are "real world" uses for compounds that specifically bind to testis cells: the purification of such cells, and in diagnosis of testis-related disorders that alter the location, number, or morphology of testis cells, such as testicular cancer (see the paragraph bridging pages 51-52). This use is credible, for example, because inhibition of testis-associated proteins results in fertilization-inhibiting substances that can be used in birth control medicaments.

Applicant provides specific, substantial and credible uses for the claimed SVPH1-27 adamalysin proteins. As a matter of Patent Office practice, a specification that provides disclosure of a utility that corresponds in scope to the subject matter sought to be patented and

that is substantial, credible, and specific *must* be taken as sufficient to satisfy the utility requirement of 35 U.S.C. §101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility.

The teachings put forth by Applicant in this specification are supported by art as discussed above and one of skill in the art would have no reason to question the objective truth of Applicant's statements of utility. This was confirmed by a later published manuscript disclosing an identical sequence which is referred to in that publication as "ADAM 20", see Hooft van Huijsduijnen, *Gene* 206: 273-282, 1998 (reference C5 of the IDS dated July 9, 2003, a copy is provided herein for your convenience). As did the Applicant in the earlier filed application, Hooft van Huijsduijnen recognizes that this protein is an ADAM family member and also points to the similarity of "ADAM20" and the sperm cell-specific fertilins-α and β and like Applicant, Hooft van Huijsduijnen suggests that ADAM20 is related to these sperm cell-specific proteins. As a side note, SVPH1-26 is now referred in the art as ADAM20.

Just as taught by Applicant, Hooft van Huijsduijnen found that "ADAM20" is exclusively expressed in testis, and by analogy to all other testis-specific ADAMs, on mature spermatocytes. Just as Applicant taught in the earlier filed specification, Hooft van Huijsduijnen states "ADAM20...'s exclusive expression in human testis and sequence similarity with fertilins-α and –β suggests they too are expressed on sperm cells and involved in sperm maturation and/or fertilization..." "Analysis of their domains suggests that ADAM 20... could be involved in adhesion to egg cells, play a role in sperm-egg function..." see page 279, left column, second paragraph.

As did Applicant in the earlier filed application, Hooft van Huijsduijnen indicates that based on these characteristics it is possible that "ADAM20" is the functional equivalent of sperm fertilin-α (see the abstract, page 273, the first full paragraph of the left hand column of page 274 and the paragraph bridging pages 279-280).

As for the function of the disintegrin domain, Hooft van Huijsduijnen, like Applicant, indicates that ADAM disintegrin domains promote rather than disrupt cell-cell interactions and that disintegrin domains play an important role in mouse fertilin β as a ligand for egg integrin α6/β1, see page 278, left hand column. Applicant was more explicit teaching "an inhibitor of the disintegrin domain of SVPH1-26 may affect fertilization" see the specification at page 9, first paragraph.

With regard to protease activity, just as Applicant teaches, Hooft van Huijsduijnen indicates that ADAM 20 (SVPH1-26) is a functional protease, like fertilin α, TNF α convertase and ADAM 10, the structural features of the protease or catalytic domain being characteristic of the adamalysin metzinecine family of proteases, see page 27 of the Hooft van Huijsduijnen reference, the paragraph bridging the left and right columns.

Applicant has asserted specific, substantial, credible and well established utilities that are recognized by those of ordinary skill in the art for the claimed SVPH1-26 polypeptides. Therefore, for at least these reasons and the amendments to the claims, Applicant respectfully request that the rejection under 35 U.S.C. § 101 and § 112, first paragraph, be withdrawn.

CONCLUSION

Applicant submits that the presented claims are in condition for allowance. A favorable action is earnestly requested. Applicant's attorney invites the Examiner to call her at the number below if any issue remains outstanding.

Respectfully submitted,

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